24(c)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 19 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID# ND940005. Section 24(c) Special Local Need Registration. **Dicamba** (Banvel® Herbicide) in/on **Millet**.
MRID No: None
CBTS No: 14120
DP Barcode: D205893

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The State of North Dakota has issued a Section 24(c) registration for the use of Banvel® Herbicide to control annual weeds in millet. The proposed label includes instructions for application of Banvel® as a tank mixture with 2,4-D amine products registered for use on millet. State approval was granted July 12, 1994.

CONCLUSIONS

1a. CBTS concludes that the proposed application instructions are not adequate to support the requested SLN registration. The Section 24(c) label should be revised to permit

application of 3 fl oz BANVEL herbicide **per acre** in combination with 2,4-D amine products, or 4 fl oz BANVEL herbicide **per acre** when used alone. The number of applications should be limited to **one per season** and the minimum spray volume for aerial application should be increased to **2** gallons/A **in a water-based carrier**.

1b. Since the registrant has requested use of 2,4-D in a tank mix with Banvel® at rates and timing no more liberal than currently registered for 2,4-D on millet, CBTS has no objection to the proposed tank mix use.

2a. The qualitative nature of the dicamba residue in plants has been adequately delineated. The residues of concern are those currently regulated under 40CFR §180.227.

2b. The metabolism of dicamba in animals is not adequately understood. For the purpose of this Section 24(c) registration **only**, CBTS concludes that the residues of concern are those currently regulated under 40CFR §180.227.

3. CBTS concludes that there are adequate plant and animal analytical methods published in PAM II or contained in PP#1F2569 to enforce tolerances associated with this Section 24(c) registration.

4a. CBTS concludes that residues of dicamba and its 5-hydroxy metabolite in/on millet as a result of the use proposed in this Section 24(c) registration are not likely to exceed the established tolerances of 0.5 ppm for millet grain and 0.5 ppm for millet straw.

4b. CBTS concludes that food or feed additive tolerances are not required to support the requested use of dicamba in/on millet under the conditions contained in this submission.

5. Residues resulting from the proposed use of dicamba in/on millet are not likely to exceed the established dicamba millet grain and straw tolerances; consequently, CBTS concludes that secondary residues likely to occur in animal commodities are adequately covered by existing tolerances.

RECOMMENDATIONS

Provided the registrant revises the proposed label as indicated in Conclusion 1a, above, CBTS has no objection to the issuance of a Section 24(c) registration for Banvel® Herbicide use on millet, alone or as a tank mix with 2,4-D, to control annual weeds in the State of North Dakota.

Residues of dicamba in/on millet grain and millet straw resulting from this use are not likely to exceed the established tolerances.

Detailed Considerations

Background

Dicamba is a FIFRA '88 List A Chemical. The Registration Standard is dated September 1983. The Chemistry Chapters of the Dicamba SRR were issued 6/30/89.

Tolerances are established under 40CFR §180.227(a) for the combined residues of the herbicide, dicamba (3,6-dichloro-*o*-anisic acid) and its metabolite 3,5-dichloro-5-hydroxy-*o*-anisic acid in or on various raw agricultural commodities including proso millet grain at 0.5 ppm and proso millet straw at 0.5 ppm. Tolerances are established under 40CFR §180.227(b) for the combined residues of dicamba and its metabolite, 3,6-dichloro-2-hydroxy-benzoic acid in/on the fat, kidney, liver, meat, meat byproducts of ruminants and milk.

Banvel® Herbicide (EPA Reg. No. 55947-1) is a registered pesticide of Sandoz Agro, Inc. The spray concentrate formulation contains 48.2% dimethylamine salt of dicamba (equivalent to 4 lbs dicamba/gallon) as the active ingredient. The product was previously manufactured by Velsicol Chemical Corporation under EPA Reg. No. 876-25 (7/8/87, F.B. Suhre, ID#KS870001).

Section 24(c) registrations have been granted for this use in Colorado (CO920004), Nebraska (NE900001), South Dakota (SD920009) and Wyoming (WY920006). CBTS has no record of reviewing these SLN registration requests.

Tolerances are established under 40CFR §180.142 for residues of 2,4-D in/on various raw agricultural commodities including millet forage at 20 ppm, millet grain at 0.5 ppm and millet straw at 20 ppm.

Proposed Use

The application directions contained on the proposed Section 24(c) label are as follows.

> *Apply BANVEL Herbicide as a broadcast or spot treatment to emerged and actively growing weeds when millet is in the 2 to 5 leaf stage.* ***Do not apply BANVEL/2,4-D amine tankmix prior to the 3-leaf stage of the millet.***
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> *For control of listed annual broadleaf weeds:*
> - *apply 3 fl. oz. BANVEL Herbicide (0.094 lb a.i.) with 3/8 lb. a.i. 2,4-D amine; or*
> - *apply 4 fl. oz. (0.125 lb ai) BANVEL Herbicide (.125 lb a.i.) alone.*
>
> *3 to 50 gallons of diluted spray per treated acre may be applied when using ground application equipment or 1 to 10 gallons of diluted spray per treated acre when using aerial application.*

Proposed Label - CBTS requests that the registrant amend the proposed label prior to Section 24(c) registration. The SLN label should be revised to permit application of either 3 fl oz

BANVEL herbicide **per acre** in combination with 2,4-D amine products, or 4 fl oz BANVEL herbicide **per acre** when used alone to adequately reflect residue data available to support the proposed use. In addition, the label should state clearly that only **one application** of BANVEL (alone or as a tankmix) is permitted **per growing season**. We further advise that the proposed label be amended to permit aerial application in a minimum volume of **2** gallons of diluted spray per treated acre **in a water-based carrier.**

Tank Mix - The proposed label states that Banvel® Herbicide may be tank mixed with 2,4-D amine products and indicates that applications should "*follow all applicable directions, restrictions, and precautions on the 2,4-D amine product label which is registered for use on millet...Use a 2,4-D product that has consistent labeling with the crop stage timing for BANVEL.*"

CBTS does not typically require residue data on tank mixes to support their use if the individual pesticides are registered for the proposed use and their maximum allowed use rates and minimum PHIs are not exceeded. Since the registrant has requested use of 2,4-D in a tank mix at rates and timing no more liberal than currently registered, CBTS has no objection to the proposed tank mix use.

Nature of the Residue

The qualitative nature of the residue in plants has been adequately delineated. The residues of concern in or on millet plant commodities are dicamba and its metabolite, 3,6-dichloro-5-hydroxy-*o*-anisic acid.

The metabolism of dicamba in animals is not adequately understood. Ruminant and poultry metabolism studies are required in the Dicamba SRR to support reregistration of the active ingredient. For the purpose of this Section 24(c) registration **only**, CBTS concludes that the residues of concern are those currently regulated under 40CFR §180.254.

Analytical Method

The Dicamba SRR indicates that the GC/EC method (AM-0268A) published in PAM Vol. II as Method I detects residues of dicamba and 3,5-dichloro-*o*-anisic acid in plant commodities. In response to an Agency requirement to add a hydrolysis step to the analytical method, the registrant submitted a modification of AM-0268A for consideration. The GC/EC method AM-0691A/B (MRID Nos. 00162206/40233501) includes a hydrolysis step and has been validated by the registrant on numerous plant commodities. The Dicamba SRR requires that the revised method undergo an ILV and Agency validation prior to consideration as an enforcement method.

The GC/EC method, AM-0685 (MRID 00079744) detects residues of dicamba and 3,6-dichloro-2-hydroxybenzoic acid (both as the methyl ester of dicamba) in milk, muscle, liver, kidney and fat. The method has been successfully validated by the Agency using milk and ground beef samples (9/1/82, K. Zee, PP#1F2569).

CBTS concludes that there are adequate plant and animal analytical methods to enforce tolerances associated with this Section 24(c) registration.

Residue Data

Field Trial Data

No residue data were submitted to support the subject 24(c) registration.

Residue data on millet were reviewed in connection with PP# 9E2166 (4/26/79, J. Onley). Two field trials on proso millet were conducted in Nebraska to support the establishment of a tolerance for residues of dicamba and its metabolites in/on millet grain at 0.5 ppm and millet straw at 0.5 ppm. A single application of Banvel 4S, alone or as a tank mix with 2,4-D (0.5 lb ai/A) was made to proso millet. PHIs ranged from 37 days to 60 days. No residues of dicamba or its 5-hydroxy metabolite were found at the method limit of quantitation reported as either 0.01 or 0.02 ppm in millet grain or straw.

In addition to the millet field trial data described above, CBTS will translate available data from other commodities in the cereal grains group to support the requested 24(c) application.

Barley field trial data were reviewed in the Dicamba SRR (5/24/89). Spring seeded barley was treated with a single application of either the dimethylamine or the ethanol salt formation at a rate of 0.125 lb ai/A (1X) in 17 - 20 gallons of water using ground equipment. Three samples of grain were harvested 69 - 86 days after treatment. Residues of dicamba ranged from <0.01 ppm - 0.27 ppm. Residues of the 5-hydroxy metabolite ranged from <0.01 ppm - 0.04 ppm. Combined residues ranged from <0.02 ppm - 0.312 ppm.

Six field trials (CO, MT, ND-2, OK and SD) were conducted depicting combined residues of dicamba and its 5-hydroxy metabolite in or on spring and winter wheat resulting from application of either the dimethylamine or ethanol salt formulation. Twelve samples of wheat grain were harvested 20 - 89 days following ground application at 0.125 lb ai/A (1X). Residues of dicamba and its 5-hydroxy metabolite were each reported at less than the method limit of quantitation (0.01 ppm).

Based on the available data, CBTS concludes that residues of dicamba and its 5-hydroxy metabolite in/on millet as a result of the use proposed in this Section 24(c) registration are not likely to exceed the established tolerances of 0.5 ppm for millet grain and 0.5 ppm for millet straw.

Processed Commodities

The Dicamba SRR required the establishment of food/feed additive tolerances for the combined residues of dicamba and its 5-hydroxy metabolite in each milled product of millet, excluding flour, based on "*the observed 2X concentration factor in wheat*".

Subsequent to the issuance of the Dicamba SRR, CBTS (F. Griffith, 11/4/88, PP#4F3041) concluded that the wheat processing study previously reviewed was not acceptable because the grain used did not have sufficient residue in the RAC prior to processing. CBRS (L. Cheng, 4/23/93, CBRS No. 11542) has since reviewed a wheat processing study submitted in response to deficiencies cited in connection with PP#4F3041. CBRS concluded that "*Residues of dicamba did not increase in any of the processed fractions..No food or feed additive tolerances in wheat processed fractions for dicamba are necessary.*" Based on the most recent findings, CBTS concludes that food or feed additive tolerances are not required to support the requested use of dicamba in/on millet under the conditions contained in this submission.

Meat, Milk, Poultry and Eggs

Residues resulting from the proposed use of dicamba in/on millet are not likely to exceed the established dicamba millet grain and straw tolerances; consequently, CBTS concludes that secondary residues likely to occur in animal commodities are adequately covered by existing tolerances.

cc: circ., RF, Dicamba 24(c) file, Dicamba Reg Std File, DDavis.
H-7509C:CBTS:DSD:CM#2:Rm804:305-7085:dd:8/17/94.
RDI:SecHd:RSQuick:8/18/94:ActBrSrSc:MTFlood:8/18/94:ActBrChf:RALoranger:8/18/94.
Disk:DSD-3 File:DICAMBA.24C